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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,238	10/21/2005	Jan Henrik Ardenkjaer-Larsen	PS0267	8175

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

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07/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,238	ARDENKJAER-LARSEN ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 1/14/2010, in reply to the Office Action mailed 10/15/2009, is acknowledged and has been entered. Claim 18 has been amended. Claims 13-18 are pending and are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments with regard to the rejection of claims 13-18 under 35 U.S.C. 112, first paragraph, have been fully considered but are not persuasive for reasons set forth hereinbelow.

Applicant's arguments with regard to the rejection of claims 13-18 under 35 U.S.C. 102(b) as being anticipated by Barkemeyer, have been fully considered but are not persuasive for reasons set forth hereinbelow.

Applicant's arguments with regard to the rejection of claims 13-18 under 35 U.S.C. 102(b) as being anticipated by Golman, have been fully considered and are persuasive because the pulse sequences performed by Golman subsequent to the hydrogenation step appear to be directed to imaging, and there is no teaching that the sequences are capable of enabling spin-order to be transferred from protons in the hydrogenated contrast agent to polarization of a nucleus within the same molecule, as claimed. Therefore the rejection has been withdrawn.

The obviousness type double patenting rejection over the claims of copending Application Serial No. 10/526,134 has been withdrawn in view of the terminal disclaimer filed 1/14/2010.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph has been withdrawn as being overcome by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons set forth in the previous Office Action.

Applicant argues on pages 4-5 of the Response that the Office's objections are directed to a substrate compound in general, while the instant claims require that the substrate also include an imaging nuclei. Applicant asserts that the claims are not directed to 'any' unsaturated compound, but to unsaturated compounds comprising imaging nuclei, and the Office's mischaracterization of the claim ignores this limitation and improperly broadens the claim scope. Applicant submits that given the examples in

the application that one of ordinary skill in the art would know how to select an unsaturated compound based on the desired contrast agent.

This is not found to be persuasive. The recitation that the unsaturated compound comprises an imaging nuclei does not provide sufficient description of the unsaturated compound since almost any unsaturated organic compound would include at least one of hydrogen, carbon or even nitrogen atoms, which are known as MR contrast imaging nuclei. The claims are broad and the description does not provide description of specific chemical moieties used to represent the substrate that would render such a compound to be useful as a contrast agent. There is very little predictability in the art concerning any undefined species which may represent a substrate compound and which chemical moiety would represent a substrate out of an almost unlimited number of chemical species which may be possible. The specification does not provide guidance to the specific identity or physical/chemical structure of the variables which represent a substrate, other than a few examples such as amino acid, nucleotide, and because the structures of these elements are undefined, it is unclear how Applicant envisaged suitable elements to satisfy the functional requirements of the substrate. Accordingly, the claims are more broad than the disclosure provides guidance for, and the metes and bounds of which types of unsaturated compounds may be suitable for use as hydrogenatable substrate for use in producing MR contrast agent are not clearly set forth. It is noted that Applicant refers in the specification as amended to substrates "as discussed in WO 99/24080 or its U.S. equivalent, United States Patent No. 6,574,495." However, an incorporation by reference must express a clear intent to

incorporate by reference by using the words "incorporate" and "reference" (see 37 CFR 1.57(b)). In the instant case, no such statement exists, and thus there is no clear intent to incorporate by reference the subject matter that identifies a hydrogenatable, unsaturated substrate compound, and no adequate description of such a compound has been provided. A description of the identity of a suitable substrate compound is considered to be essential material to the method which is claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Barkemeyer *et al.* (*J. Magnetic Res*, 1996, p. 129-132), for reasons set forth in the previous Office Action.

Applicant argues on pages 5-6 of the Response that Barkemeyer discloses methods of transferring polarization generated by parahydrogen to heteronuclei such as ^{13}C, and describes a method of applying oscillating magnetic fields in the presence of a stationary magnetic field. Applicant asserts that Barkemeyer does not describe the use of pulses of magnetic fields in which two subsequent pulses have different orientation. Applicant asserts that moreover, Barkemeyer is not directed to a method for production of contrast agents, and that the magnetic field treatment of the present invention further

increases the degree of polarization of the MR contrast agent, especially polarization of carbon atoms within the MR contrast agent.

This is not found to be persuasive. It is interpreted by the examiner that Barkemeyer meets the instant method steps including the use of pulses of magnetic field in which two subsequent pulses have different orientation. See for example pulse sequences on page 130, Figure 1, including 90 degree, 180 degree, etc. pulses (i.e. pulses which differ in orientation). With regard to the argument that Barkemeyer is not directed to production of contrast agents, this is not found to be persuasive. The intended use of the hydrogenated substrate is not given patentable weight to distinguish over Barkemeyer because the intended use of the claimed invention must result in a structural difference between the claimed invention from the prior art. Barkemeyer teaches hydrogenation of an unsaturated substrate using hydrogen gas enriched in para-hydrogen according to methods steps which are readable upon the claimed method steps.

Conclusion

No claims are allowed at this time.

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered, they are deemed unpersuasive. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is (571)272-9928. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday 9 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS